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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,723

03/19/2004

Scot R. Weinberger

CiphBio-12

8261

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7590

12/17/2004

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EXAMINER

SOUW, BERNARD E

ART UNIT

PAPER NUMBER

2881

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,723

Applicant(s)

WEINBERGER, SCOT R.

Examiner

Bernard E Souw

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4, 7-10, 12-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp (USPAT 6,706,530), hereinafter Hillenkamp'530, in view

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of Odom et al. (USPAT 6,451,616) and Gauthier et al. (Anal. Chim. Acta, 1991, **246**, pg.211-225).

► Regarding claim 1, Hillenkamp'530 discloses a method for producing a preponderance of gas phase ions having higher order charge states during laser desorption ionization of an analyte, as recited in the Abstract by the term MALDI (matrix assisted laser desorption/ionization) and in Col.7/ll.47-60, wherein the limitation of "*ions having higher order charge states*" is specifically recited in Col.7/line 57, the method comprising: irradiating the analyte in the presence of energy absorbing molecules at a mid-IR wavelength, as recited in Col.7/ll.43-50.

Although the limitation of "*a mid-IR wavelength being offset from an IR absorption maximum of the energy absorbing molecules*" is inherently comprised in Hillenkamp'530's method, said limitation is not expressly recited by Hillenkamp'530.

Odom et al. disclose a laser desorption method followed by ionization similar to Hillenkamp'530's, as recited in Col.6/ll.53-67 and Col.7/ll.1-10. Odom's IR-laser wavelength is "*offset from an IR absorption maximum of the energy absorbing molecules*", as expressly recited in Col.7/ll.5-10. Off-resonance dissociation and fragmentation of molecules are also described by Gauthier et al., as recited in the article title, whereas the pertinent ionization is obvious in reference to Gauthier's Eqs. 6-18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use in Hillenkamp'530's MALDI process a mid-IR laser wavelength that is offset from an IR absorption maximum of the energy absorbing molecules, as suggested by Odom et al. and Gauthier et al., since there are plenty of

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laser types that can be used for such off-resonance processes, such that the choice of laser type is not critical, and hence, the MALDI process is much more easier to implement.

► Regarding claim 2, the limitation that the analyte is within a matrix of an energy absorbing molecules is inherent in Hillenkamp'530's, Odom's, as well as Gauthier's method, as generally known in the art of MALDI process. This Official Notice is supported by Hutchens et al. (USPAT 5,719,060), as recited in Col.12/II.41-49.

► Regarding claim 4, the use of a fixed wavelength mid-IR laser is recited by Hillenkamp'530 in Col.7/II.50-55 and Col.14/II.22-27.

► Regarding claim 7, the step of detecting a plurality of higher order charge state gas phase ions is implicitly recited by Hillenkamp'530 in Col.17/II.61-67 + Col.18/II.1-2, Col.18/II.7-10 and Col.19/II.8-38.

► Regarding claims 8-10, the steps of using mass spectrometer (MS) and detecting the ion masses by mass spectral analysis are recited by Hillenkamp'530 in the Abstract, Col.1/II.12-38 and Col.14/II.53-58.

► Regarding claims 12 and 13, the steps of using diverse types of MS including tandem MS and QqTOF are expressly recited by Hillenkamp'530 in Col.3/II.40-44.

► Regarding claim 14, the steps of selecting, fragmenting performing mass spectral analysis an ion species is recited by Hillenkamp'530 in Col.1/II.17-37.

► Regarding claims 15-18, the entire claimed range of ion masses is covered by Hillenkamp'5430 in Col.17/II.61-67, Col.18/II.7-10 and Col.19/II.8-38.

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- ▶ Regarding claim 19, the step of fragmenting by collision induced dissociation is recited by Hillenkamp'530 in Col.1/ll.24-25, and by Gauthier et al. in the Abstract.
- ▶ Regarding claim 20, all claim limitations beyond what is readily comprised in previously rejected claim 19, e.g., referring to the term "*scan*", are known in the art as being inherent to mass spectrometers as used by Hillenkamp'530, since ion identification in most MS are performed by "scanning" the MS.
- ▶ Regarding claims 24, 25 and 28, the recitations of protein and amino acid sequence as well as the steps for their identification by means of a database, are recited by Odom et al. in Col.6/ll.23-25.

5. Claims 3 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp in view of Odom et al. and Gauthier et al., and further in view of Peters et al. (US PG PUB 2003/0228700).

Hillenkamp'530 as modified by Odom et al. and Gauthier et al. show all the limitations of claims 3 and 21-23, as previously applied to claim 1, except the recitation of using photoactive components of a SEND surface, a SELDI probe, or both.

Peters et al. disclose an IR-MALDI process using a matrix, similar to Hillenkamp'530's, wherein the energy absorbing molecules are photoactive components of a SEND surface and/or SELDI probe, as recited in sect.[0092], wherein the step of contacting the probe-adsorbed analyte with energy absorbing molecules is also inherent in Peters's.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use in Hillenkamp'530's IR-MALDI process as modified by Odom et al. and Gauthier et al. photoactive components of a SEND surface or a SELDI probe, as suggested by Peters et al., since the surface-enhancement thereby involved renders a more efficient utilization of the laser energy.

6. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp in view of Odom et al. and Gauthier et al., and further in view of Doroshenko et al. (USPAT 6,683,300).

Hillenkamp'530 as modified by Odom et al. and Gauthier et al. show all the limitations of claims 5 and 6, as previously applied to claim 1, except the use of a tunable laser, more specifically a tunable OPO laser. These limitations are rendered obvious by Doroshenko et al., as recited in Col.8/ll.6-9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use in Hillenkamp'530's MALDI process a mid-IR laser wavelength that is tunable, as suggested by Doroshenko et al., since by tuning the laser wavelength to the absorption maximum of the energy absorbing molecules an on-resonance dissociation and fragmentation of molecules can be achieved, and hence, the laser energy can be even more effectively utilized.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp in view of Odom et al. and Gauthier et al., and further in view of Hofstadler et al. (USPAT 6,342,393).

Hillenkamp'530 as modified by Odom et al. and Gauthier et al. show all the limitations of claim 11, as previously applied to claim 1-10, except the use of a tandem mass spectrometer and a tandem mass spectral analysis. These limitations are rendered obvious by Hofstadler et al., as recited in Col.7/ll.50-67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use in Hillenkamp'530's MALDI process a tandem mass spectrometer and a tandem mass spectral analysis as suggested by Hofstadler et al., since higher mass resolutions, as well known to tandem MSs, can thus be obtained.

8. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillenkamp in view of Odom et al. and Gauthier et al., and further in view of Crooke et al. (USPAT 6,656,690).

Hillenkamp'530 as modified by Odom et al. and Gauthier et al. show all the limitations of claims 26 and 27, as previously applied to claim 1-25, except the steps of determining amino acid sequence by calculating differences in the detected masses and querying a protein sequence database. These limitations are rendered obvious by Crooke et al., as recited in Col.32/ll.10-24 in reference to Fig.26, wherein the step of calculating mass differences is specifically recited in Col.32/line 13, whereas the step of

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querying a protein sequence database is readily rendered obvious by Odom et al. in Col.6/ll.23-25, as previously applied to claim 28.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the amino acid sequence by calculating differences in masses detected in Hillenkamp's 530's MALDI process, as suggested by Crooke et al., since said step is conventional for that purpose.

Communications

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard E Souw whose telephone number is 571 272 2482. The examiner can normally be reached on Monday thru Friday, 9:00 am to 5:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R Lee can be reached on 571 272 2477. The central fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications as well as for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0956.

bes
December 2, 2004


JOHN R. LEE
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